JUN 1 9 2001

K011172

510(K) Summary

2/28/01

Company: Arthrex, Inc.
Address: 2885 South Horseshoe Drive, Naples, Florida 34104
Phone: (941) 643-5553 (ext. 171)
Fax: (941) 435-7191
Contact: Brette Masino
Regulatory Affairs Specialist

Trade Name: Arthrex Bio-Transfix
Common Name:
Classification: Pin, Fixation, Smooth, Non-Metallic

Description:
The Arthrex Bio-Transfix, composed of poly(L-lactide), is a cannulated pin having a diameter of approximately 5 mm and an overall length of 50 mm. One end is tapered 11.684 mm to a minor diameter of 1.422 mm. The other end has three barbs for cortical fixation and a spherical fitting for its driver.

Intended Use:
The **Arthrex Bio-Transfix** is intended to provide ACL graft fixation in the femur in orthopaedic procedures.

Substantial Equivalence:
By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

The differences between the Arthrex Bio-Transfix and the predicate device do not raise any different questions regarding safety and effectiveness. Furthermore, the material is well characterized, and has been used in predicate devices with similar indications. The device, as designed, is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vernon C. Brown
Manager, Regulatory Affairs
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K011172
Trade Name: Arthrex Bio-Transfix
Regulation Number: 888.3030, 888.3040 and 888.3040
Regulatory Class: II
Product Code: MNU, JDR and HTY
Dated: March 19, 2001
Received: April 17, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K011172

Device Name: Arthrex Bio-Transfix

Indications For Use:

The **Arthrex Bio-Transfix** is intended to provide ACL graft fixation in the femur in orthopedic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011172

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)